

S/N 10/565,911

In response to the Office Action dated November 24, 2009

Remarks

Favorable reconsideration and reexamination of this application are respectfully requested.

Claim Rejections – 35 USC § 103

Claims 1 and 2 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. (U.S. 5,330,835) in view of Yamamoto et al. (U.S. 5,431,917).

Claims 1 and 2 are directed to a heat resistant capsule where curdlan is used as a capsule covering film matrix of the capsule covering film and contained at an amount of 80% by weight or more relative to a total weight of the capsule covering film matrix.

Kikuchi discloses a seamless capsule which comprises a hydrophilic substance and a film for coating the hydrophilic substance (see Abstract and col. 1, lines 53-55). As noted in the rejection, Kikuchi does not disclose the use of curdlan for the capsule covering film matrix of the seamless capsule as required in claims 1 and 2.

Yamamoto discloses a hard capsule for pharmaceutical drugs which is comprised of a water-soluble cellulose derivative as a capsule base, an auxiliary for gelation, and a gelatinizing agent. Yamamoto discloses that curdlan can be used as the gelatinizing agent and be contained in ranges of 0.1 to 0.5% by weight (col. 3, lines 29-32). Yamamoto further discloses producing a hard capsule wherein 0.15 to 0.3 parts by weight of the gelatinizing agent is used (Claim 9, col. 8, lines 28-30). However, Yamamoto does not disclose, or even suggest, that curdlan be used as the main component or matrix material of the capsule shell where curdlan is used in an amount of at least 80% by weight. The 80% by weight, as required in claims 1 and 2, is an order of magnitude more than the 0.15 to 0.3 parts by weight suggested by Yamamoto. Therefore, Yamamoto does not disclose, teach or suggest the features of claims 1 and 2 when combined with Kikuchi. Applicants respectfully request the rejection be withdrawn for at least the foregoing reasons.

Claims 4-10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Kikuchi et al. (U.S. 5,330,835) in view of Kiefer et al. (U.S. 6,174,466) further in

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view of Kamaguchi et al. (WO 03/043609). Applicants respectfully traverse this rejection

Claim 4 is directed to a process for producing a heat resistant capsule, and requires simultaneously extruding a capsule filler solution through the first nozzle, a capsule covering film solution containing curdlan, through the second nozzle, and an oil solution through the third nozzle to form a composite jet, and releasing the composite jet into a heated oil solution. The temperature of the oil solution extruded through the third nozzle is lower than that of the heated oil solution, the oil solution has a temperature of 20 to 65 °C and the heated oil solution has a temperature of 80 °C or more.

A problem associated with using curdlan is that during production of the capsule, gelling and plugging of the nozzles occurs when curdlan solution is extruded in a solidifying solution from the nozzles. The present invention solves this problem by having oil flow, at a temperature of 20 to 65 °C, through the outer-most nozzle. By maintaining a temperature of 20 to 65 °C, the capsule droplet is kept in a low set condition known as "thermal reversible low set gel", which occurs at temperatures below 80 °C. This low set condition prevents gelling and plugging near the outlet of the nozzles. The outer-most nozzle is open to the solidifying solution (heated oil solution) which is maintained at a temperature of 80 °C or higher. As the capsule droplet leaves the nozzles, it is slowly contacted with the solidifying solution and solidifies in a high set gel condition known as "thermal irreversible high set gel", which occurs at temperatures of 80 °C or higher, thereby forming a curdlan capsule.

Kikuchi discloses a seamless capsule that comprises a hydrophilic substance and a film for coating the hydrophilic substance (see Abstract and col. 1, lines 53-55). First, and as noted in the rejection, Kikuchi does not disclose the use of curdlan for the shell composition of the seamless capsule.

Second, Kikuchi further discloses that the seamless capsule is produced by three nozzles and uses the third or outer-most nozzle for shell composition. If Kikuchi used curdlan and extruded a shell composition containing curdlan from the outer-most nozzle into a heated oil solution of 80 °C or higher, the shell composition would make immediate contact with the oil solution of 80 °C or higher and cure, resulting in a high set gel and plugging the nozzle. This is different than the outer-most nozzle of claim 4,

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which is used for an oil solution of 20 to 65 °C, and from which the capsule composition is released into the solidifying solution in which the curdlan capsule would solidify.

Third, Kikuchi discloses injecting the jet into a vegetable oil bath of 12 °C (col. 4, lines 61-62), which is a much lower temperature than the 80 °C required for the heated oil solution in claim 4. Kikuchi does not meet the limitations of the claims.

Kiefer discloses a method for making seamless capsules that does not remedy the deficiencies of Kikuchi. First, Kiefer does not disclose the use of curdlan for the shell composition of the seamless capsule. Second, Kiefer discloses using a concentrically aligned multiple nozzle system having at least one outer nozzle 105 and an inner nozzle 106 (col. 5, lines 50-51). The inner nozzle 106 supplies the core material and the outer nozzle 105 supplies the shell material (col. 5, lines 52-56). A first, upper duct 108 extends downwardly from the multiple nozzle system 100 and the upper part of the first duct 108 is surrounded by a feed wiew 107 (col. 5, lines 57-59 and Fig. 1). The coaxial jet of the shell material and the core material is introduced into a flow of a heated carrier liquid, at 100 °C, in an open-ended first duct 108 to form capsules and to transport the capsules into a cooled liquid, of 0 to 30 °C, in a second duct 110 in order to solidify the capsules (claim 1, col. 9, line 67 to col. 10, line 4, col. 10, lines 5-8 and Fig. 1). The rejection then appears to equate the first duct 108 with the third nozzle of claim 4.

Keifer does not disclose three concentrically disposed nozzles as required in claim 4. And, if the first duct 108 is equated with the third nozzle of claim 4, the duct contains heated coconut oil, supplied by the feed wiew 107, and maintained at 100 °C, which is much higher than the 20 to 65 °C required for the oil solution of the third nozzle of claim 4. As discussed above, a temperature of more than 80 °C would result in the high set gel condition and solidify a curdlan capsule. But, Keifer is maintaining a temperature of 100 °C to prevent the shell material from solidifying (col. 9, line 67 to col. 10, line 4) and uses cooled liquid of about 0 to 30 °C to solidify the capsules (col. 10, lines 5-8). This is opposite of what is required in claim 4 where a lower temperature is maintained to prevent solidification and a higher temperature is maintained to cause solidification. Therefore, Keifer neither suggests nor considers capsules made from curdlan and does not suggest or teach the features of claim 4.

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Kamaguchi discloses a non-gelatinous capsule which contains starch hydrolyzate and a gelatinizing agent. The gelatinizing agent can be curdlan (col. 4, line 17). The gelatinizing agent is contained only in an amount of 0.5 to 30% by weight, preferably 1 to 15% by weight, based on the total weight of the solid content in the capsule shell composition (col. 4, lines 29-31). Kamaguchi discloses that the seamless capsule can be produced by a multiple nozzle, which is a doublet or more (col. 5, lines 46-53). Kamaguchi discloses releasing the jet stream, consisting of the shell composition and the content, from the nozzle into a cooling solution of a vegetable oil at a temperature of not more than 20 °C to obtain the capsule (col. 6, lines 23-29). Kamaguchi does not disclose or suggest that the heated oil solution be more than 80 °C as required in claim 4.

Therefore, even if the features of Kikuchi, Keifer and Kamaguchi are combined, the features of claim 4 are not met. The rejection of this claim should be withdrawn.

Claims 6-8 are allowable at least by virtue of their dependence on independent claim 4 and the rejection these claims should be withdrawn. Applicants do not concede the correctness of the rejection.

Claim 5 is directed to a process for producing a heat resistant capsule, and requires simultaneously extruding a capsule filler solution through the first nozzle, a liquid substance for isolating the capsule filler solution and a capsule covering film through the second nozzle, a capsule covering film solution through the third nozzle, and an oil solution through the fourth nozzle to form a composite jet, and releasing the composite jet into a heated oil solution. The capsule covering film solution contains curdlan, and a temperature of the oil solution which is extruded through the fourth nozzle is lower than that of the heated oil solution. The oil solution has a temperature of 20 to 65 °C and the heated oil solution has a temperature of 80 °C or more. Claim 5 is allowable over Kikuchi, Kiefer, and Kamaguchi at least for the reasons discussed above for claim 4.

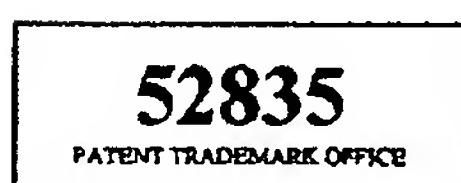
Claims 9-10 are allowable at least by virtue of their dependence on independent claim 5 and the rejection these claims should be withdrawn. Applicants do not concede the correctness of the rejection.

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Favorable reconsideration and withdrawal of the rejection are respectfully requested.

In view of the above amendments and remarks, Applicants respectfully request favorable reconsideration of this application in the form of a Notice of Allowance. If any questions arise regarding this communication, the Examiner is invited to contact Applicants' representative listed below.




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Respectfully submitted,

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